OCT 3 0 2001 K013422

GE Medical Systems
General Electric Company
P O Box 414 Milwaukee, WI 53201

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Submitter Larry A. Kroger, Ph.D.
Senior Regulatory Program Manager
Telephone: (262) 544-3894, FAX: (262) 544-3863
Date Prepared: September 7, 2001

PRODUCT IDENTIFICATION

Name: CardIQ Function -

Classification Name: Accessory to Computed Tomography System

Classification Number: 892.1750

Manufacturer : General Electric Medical Systems
3200 N. Grandview Blvd.
Waukesha, WI 53188

Distributor: General Electric Medical Systems, Milwaukee, WI

Marketed Devices The CardIQ Function is substantially equivalent to the device listed below:

Model:	Ventricular Analysis Toolkit Option
Manufacturer:	General Electric Medical Systems, Milwaukee, WI
510(k) #:	K000315

Device Description:
CardIQ Function, also called CT-MASS, is a software package for the GE advantage Windows (AW) workstation. CardIQ Function is an image post processing and analysis package that allows the user to obtain the clinical relevant anatomical and functional information from Cardiac CT images to facilitate cardiovascular disease diagnosis and risk management. In particular it supports:

- Ability to input, load and display multi-phase, multi-location Cardiac CT image series. Typically, these images are images along the short axis of the heart, reformatted from axial cardiac CT images.
- Display 3D or 4D image series as a function of either time variation within R-R period or locations along long and short axis.

- Manual or semi-automatic contour detection of either epicardium or endocardium edges of ventricular chambers.
- Measure and display ventricular wall motion, wall thickness, myocardium mass, ventricle volume and ejection fraction.
- Generating a patient/physician report, which contains cardiac function measurement data, sample source images and processed images.

Indications for Use :
The CardIQ Function is a software package that can be used in conjunction with CT Cardiac images to (semi-automatically) calculate and display various Left Ventricular and Right Ventricular functional parameters such as End Systolic and End Diastolic Volumes, Stroke Volume, LV Ejection Fraction including Peak Filling and Ejection Rates, Myocardial Mass Calculations, Regional Wall Motion Display and Analysis. When interpreted by a trained physician, the software aids in assessment of cardiac function and in determination of cardiovascular disease diagnosis and management.

Comparison with Predicate:
CardIQ Function is an image post processing and analysis package that allows the user to obtain the clinically relevant anatomical and functional information from Cardiac CT images. This application is a natural extension to the MR Ventricular Analysis Toolkit, which now supports the processing of cardiac images from CT imaging devices.

Device Name	FDA Clearance Number
Ventricular Analysis Toolkit Option	K 000315

Adverse Effects on Health :
The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

Conclusions:
The CardIQ Function does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the CardIQ Function to be equivalent to those of Ventricular Analysis Toolkit Option (K000315).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2001

General Electric Medical Systems
% Mr. Reiner Krumme
Manager, Medical Division
TUV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K013422
Trade/Device Name: CardIQ Function
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: October 9, 2001
Received: October 16, 2001

Dear Mr. Krumme:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K01 3422

Device Name: CardIQ Function

Indications for Use

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801-109)

David G. Seyam

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013422